## **AMENDMENT**

It is respectfully requested that the application be amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as follows:

## **IN THE CLAIMS:**

Kindly amend the claims, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

- 1. (Amended) A method of non-invasive genetic immunization in an animal and/or a method of inducing a systemic immune response or systemic therapeutic response to a gene product, in an animal, comprising contacting skin of the animal with a bacterial vector that contains and expresses a nucleic acid molecule encoding the gene product, in an amount effective to induce the response.
- 2. (Cancelled) The method of claim 1 wherein the bacterial vector is gram positive or gram negative.
- 3. (Amended) The method of claim 2 1 wherein the bacterial vector is gram positive.
- 4. (Amended) The method of claim 2 1 wherein the bacterial vector is gram negative.
- 5. (Cancelled) The method of claim 3 wherein the bacterial vector is chosen from the group consisting of *Bacillus, Clostridium, Streptococcus* and *Staphylococcus*.
- 6. (Amended) The method of claim [4] 1 wherein the bacterial vector is chosen from the group consisting of <u>Bacillus</u>, <u>Clostridium</u>, <u>Streptococcus</u>, <u>Staphylococcus</u>, <u>Escherichia</u>, <u>Salmonella</u>, <u>Bordetella</u>, <u>Haemophilus</u> and <u>Vibrio</u>.
- 7. (Original) The method of claim 6, wherein the bacterial vector is Salmonella.

- 8. (Original) The method of claim 7, wherein the bacterial vector is Salmonella typhimurium.
- 9. (Original) The method of claim 1 wherein the nucleic acid molecule is exogenous or heterologous to the vector.
- 10. (Original) The method of claim 1 wherein the response comprises a systemic immune response.
- 11. (Original) The method of claim 1 wherein the vector comprises and expresses an exogenous nucleic acid molecule encoding an epitope of interest.
- 12. (Original) The method of claim 1 wherein the vector comprises and expresses an antigen.
- 13. (Original) The method of claim 1 wherein the vector comprises and expresses a therapeutic product.
- 14. (Original) The method of claim 1 wherein the nucleic acid molecule encodes an epitope of interest and/or an antigen of interest and/or a nucleic acid molecule that stimulates and/or modulates an immunological response and/or stimulates and/or modulates expression comprising transcription and/or translation of an endogenous and/or exogenous nucleic acid molecule.
- 15. (Original) The method of claim 4 wherein the exogenous nucleic acid molecule encodes one or more of an antigen or portion thereof, or one or more of an epitope of interest, from a pathogen.
- 16. (Amended) The method of claim 4 wherein the exogenous nucleic acid molecule encodes one or more of: influenza hemagglutinin, influenza nuclear-protein, influenza M2, tetanus toxin C-fragment, anthrax protective antigen, anthrax lethal factor, rabies glycoprotein, HBV surface antigen, HIV gp 120, HIV gp 160, human carcinoembryonic antigen, malaria CSP, malaria SSP, malaria MSP, malaria pfg, and mycobacterium Mycobacterium tuberculosis HSP.

- 17. (Original) The method of claim 4 wherein the exogenous nucleic acid molecule encodes an immunomodulator.
- 18. (Cancelled) The method of claim 3 wherein the response is induced by the vector expressing the nucleic acid molecule in the animal's cells.
- 19. (Cancelled) The method of claim 11 wherein the cells comprise epidermal cells.
- 20. (Amended) The method of claim 3 wherein the response comprises an immune response against a pathogen or a neoplasm.
- 21. (Original) The method of claim 1 wherein the animal is a vertebrate.
- 22. (Original) The method of claim 14 wherein the vertebrate is a bird or mammal.
- 23. (Original) The method of claim 15 wherein the bird or mammal is a human or a companion or domesticated or food-or feed-producing or livestock or game or racing or sport animal.
- 24. (Original) The method of claim 16 wherein the animal is a cow, a horse, a dog, a cat, a goat, a sheep, a pig, or a chicken, or a duck, or a turkey.
- 25. (Original) The method of claim 1 wherein the bacterium comprises an exogenous or heterologous nucleic acid molecule encoding the gene product for the response.
- 26. (Original) The method of claim 21 wherein the nucleic acid molecule is exogenous or heterologous and encodes an epitope of interest and the method is for inducing a systemic immunological response.
- 27. (Cancelled) The method of claim 21 wherein the nucleic acid molecule is exogenous or heterologous and encodes one or more influenza epitopes of interest and/or one or more influenza antigens.

- 28. (Original) The method of claim 1 wherein the vector is matched to, or a natural pathogen of, the animal.
- 29. (Original) The method of claim 1 comprising application of a delivery device including the vector to the skin of the animal.
- 30. (Original) The method of claim 25 further comprising disposing the vector in and/or on the delivery device.
- 31. (Original) The method of claim 25 further comprising at least one application of the delivery device including the vector to the skin of the animal.
- 32. (Original) The method of claim 27 further comprising multiple applications of the delivery device including the vector to the skin of the animal.
- 33. (Cancelled) The method-of-claim-1 wherein the vector induces an anti-tumor effect in the animal by expressing an oncogene, a tumor-suppressor gene, or a tumor-associated gene.
- 34. (Cancelled) The method of claim 10, wherein the immunomodulator comprises a costimulator and/or a cytokine.
- 35. (Original) The method of claim 1 wherein the response is against *Clostridium tetanus* infection.
- 36. (Original) The method of claim 1 wherein the exogenous nucleic acid molecule encodes tetanus toxin C-fragment.
- 37. (Original) The method of claim 1 wherein the exogenous nucleic acid molecule encodes an antigen or epitope of tetanus toxin.

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- 38. (Original) The method of claim 29 wherein the hair is not removed from the skin prior to applying the delivery device to the skin of the animal.
- 39. (Original) The method of claim 29 wherein the hair is removed from the skin prior to applying the delivery device to the skin of the animal.
- 40. (New) The method of claim 6, wherein the bacterial vector is Escherichia coli.